IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION Master File No. 2:12-MD-02327 MDL 2327

THIS DOCUMENT RELATES TO ALL CASES

JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

NOTICE TO TAKE ORAL DEPOSITION OF DEFENDANT THROUGH DESIGNATED WITNESSES

TO: Defendants ETHICON, INC. and Johnson & Johnson, Inc. (hereinafter "Defendants") and their Attorneys of Record.

Please take notice that pursuant Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiffs, by and through their counsel, will take the videotaped deposition of Defendants corporate designees at an agreed upon date and location. The witness(es) shall be prepared to testify concerning the subject matters identified in Exhibit "A", attached hereto. The witness shall produce documents identified in Exhibit "B", attached hereto, prior to the deposition. The deposition will be taken before a person authorized by law to administer oaths, pursuant to Rule 28 of the Federal Rules of Civil Procedure, and will continue day-to-day until the examination is completed.

DEFINITIONS

All definitions and rules of instructions set forth in Fed. Rule Civ. P. 30(b)(6) shall apply to all requests for information herein. To the extent a term commonly in use in the medical device industry is not defined herein, it shall be understood to be consistent with the meaning commonly ascribed to that term in the medical device industry.

- 1. "Concerning" means referring to, describing, evidencing, or constituting. See LR Civ. P 26.2(c)(7).
- 2. "Defendants", "Ethicon, Inc.", "Johnson & Johnson Inc.", "you" or "your" refers to, without limitation, Ethicon, Inc., Johnson & Johnson Inc., and all business entities with which it is or has been affiliated, together with any predecessor, successor, parent, or subsidiary entity as well as any officer, director, employee, attorney, agent, or representative of any such other business entity previously described herein.
- 3. "Document" is synonymous in meaning and equal in scope to the usage of this term in Rule 34(a) of the Federal Rules of Civil Procedure and expressly includes writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any medium from which information can be obtained either directly or, if necessary, after translation by you into a reasonably usable form. A draft or non-identical copy is a separate document. *See* LR Civ. P. 26.2(c)(2); *see also* FR Civ. P 34(a).
- 4. "TVT" means the TVT Tension Free Vaginal Tape System (Retropubic) cleared by the FDA on or about January 01, 1998, which was developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI). The term "TVT" also includes any kits or tools designed to be sold with the TVT including, but not limited to the TVT-AA and TVT-D.
- 5. "TVT Products" includes the TVT, TVT-O, TVT-A, TVT-E and TVT-S as defined below.
- 6. "TVT-O" means the TVT-Obturator device cleared by the FDA on or about December 08, 2003 which was developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI).

- 7. "TVT-A" means the TVT-Abbrevo Tension Free Vaginal Tape cleared by the FDA on or about July 1, 2010 which was developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI).
- 8. "TVT-E" means the TVT-Exact device cleared by the FDA on or about March 16, 2010, which was developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI).
- 9. "TVT-S" means the TVT-Secur device cleared by the FDA on or about November 28, 2005 which was developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI).
- 10. "Prolene" mesh means the surgical mesh products constructed of knitted filaments of extruded polypropylene identical in composition to Prolene Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.).
- 11. "Prolene Hernia mesh" means the surgical mesh products constructed of knitted filaments of extruded polypropylene identical in composition to Prolene Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.). used in "Old Construction 6 mil" hernia mesh, Prolene Hernia mesh Revisions 2, Prolene Hernia mesh Revision 3, Prosima, Vypro I, Vypro II and Ultrapro.
- 12. "Professional Education" means the methods and materials used to educate and train physicians and sales representatives on the TVT device and procedure.
- 13. "Relevant Time Period" means the time period from when you first developed, designed, distributed, licensed, manufactured, marketed or sold TVT to the present.

November 14, 2013

PLAINTIFFS' CO-LEAD COUNSEL

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EXHIBIT "A"

DEPOSITION SUBJECT MATTER

Pursuant to Rule 30(b)(6), the deponent(s) must have knowledge and shall be able to testify concerning the following subject matters:

- 1. Professional education materials.
 - a. Dates of use for all Professional education materials. How they were archived.
 - b. Manner in which training is created, updated, and communicated.
 - i. How physician training is tracked.
 - How the company tracks which physician training materials are tracked for each physician who attends a training session is tracked.
 - iii. Manner in which physicians were selected for training.
 - iv. How physicians are paid/incentivized.
 - v. How they were evaluated/monitored/followed.
 - c. Identities of all persons who had input into creating training.
 - d. Methods used to train physicians.
 - i. Preceptorships/proctorships
 - 1. Identities of the preceptors/proctors
 - 2. How they were paid, incentivized, etc.
 - 3. How they were selected, evaluated, monitored, followed.
 - ii. Cadaver labs
 - iii. Telesurgeries

- How and by whom these materials are created, updated, communicated, disseminated and archived.
- iv. Speaker events
- v. Webcasts
 - How and by whom these materials are created, updated, communicated, disseminated and archived
- vi. Sales representatives
 - 1. Their role in training and updating physicians.
- vii. Written materials
 - How and by whom these materials are created, updated, communicated, disseminated and archived.
- e. Any and all credentialing programs supported by Ethicon.
- f. Policies and procedures for certifying physicians trained are qualified to implant the TVT device.
 - How and by whom these policies are created, updated, communicated, disseminated and archived.
- 2. Sales Representative education materials.
 - Dates of use for all Sales Representative education materials. How they were archived.
 - b. Manner in which training is created, updated, and communicated.
 - i. How sales representative training is tracked.
 - ii. Manner in which sales reps were selected for training.
 - iii. How sales reps are paid/incentivized.

- iv. How they were evaluated/monitored/followed.
- c. Identities of all persons who had input into creating training.
- d. Methods used to train sales reps.
 - i. Materials/resources available to sales representatives
 - Databases for storing, communicating and tracking sales representative training materials
- Communications with physicians including Dear doctor letters and the method of distribution.

EXHIBIT "B"

DOCUMENT REQUESTS

Please produce:

- 1. All documents relied upon by the deponent in preparing for this deposition.
- 2. The following documents for the training and education of physicians, including but not limited to:
 - a. Final and draft versions of all professional education materials provided in index on June 26, 2013.
 - b. Copy approval forms for all professional education materials.
- 3. Final versions of all additional professional education materials identified subsequent to the index provided on June 26, 2013.
- 4. Video and audio recordings of all live training sessions including the names of the surgeons involved.
 - 5. Written notes taken from all live training sessions.
 - 6. Copy approval forms for all professional education materials.
- 7. The tracking and recordation documents for physician training including specifications of the program, the physicians who attended and physician training materials provided.

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CERTIFICATE OF SERVICE

I hereby certify that on November 14, 2013, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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